DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 27, 2014

Creganna-Tactx Medical
% Niall Fox
Sr. Regulatory Affairs Specialist
Parkmore West
Galway, Ireland

Re: K140338
Trade/Device Name: Creganna-Tactx Lotus Introducer Set (small), Creganna-Tactx Lotus Introducer Set (large)
Regulation Number: 21 CFR 870.1340
Regulation Name: Introducer Catheter
Regulatory Class: Class II
Product Code: DYB
Dated: July 18, 2014
Received: July 23, 2014

Dear Niall Fox,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: _____ Lotus Introducer Set _____

Indications for Use:

The Lotus Introducer Set is intended to provide femoral access to the vascular system.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

General Information

Date :	January 31, 2013
Classification	Class II, 21 CFR § 870.1340, Catheter introducer - Product Code: DYB
Trade Name	Creganna-Tactx Lotus™ Introducer Set
Model Numbers	139809-01, 139809-02
Submitter	Creganna-Tactx Medical Parkmore West Galway, Ireland
Regulatory Contact	Niall Fox Senior Regulatory Affairs Specialist Creganna-Tactx Medical Parkmore West Galway, Ireland Tel: + 91 474457 Email: niall.fox@creganna.com

Intended Use

The Lotus™ Introducer Set is intended to provide femoral access to the vascular system.

Predicate Device

RetroFlex3 Introducer Set cleared via 510(k) K093877. It is manufactured by Edwards Life Sciences.

Device Description

The Lotus™ Introducer Set is a sterile, single-use introducer catheter that provides percutaneous access to the femoral artery for introduction of catheter-based devices into the vascular system. The Lotus Introducer Set will be inserted into the femoral artery using conventional minimally invasive catheterization techniques. The Lotus Introducer Set is composed of a dilator and an introducer sheath with a flush port. The design features a PTFE liner on the ID of the introducer sheath and an external coating on both the introducer sheath and the dilator. When activated, the external hydrophilic coating increases the lubricity of the surface to aid in delivery.

Materials

The Creganna-Tactx Lotus™ Introducer Set assembly is comprised of materials that are commonly used in medical device applications.

Testing

In vitro testing was performed on the Creganna-Tactx Lotus™ Introducer Set to assure reliable design and performance in accordance with applicable standards, intended use and user requirements. The non-clinical tests performed by the company include:

- Introducer shaft pressure integrity
- Corrosion resistance
- Introducer shaft tensile strength
- Tensile strength of Hub to Introducer Shaft joint
- Tensile strength of Luer to Dilator Shaft joint
- Tensile strength of Dilator Shaft
- Introducer valve leakage, unloaded
- Introducer valve leakage, loaded with device/ loaded with guidewire
- Insertion / Removal force of Dilator
- Dilator to guidewire interface – Insertion / Removal
- Kink testing
- Particulate Testing

Biocompatibility

- Cytotoxicity
- Sensitization
- Irritation / intracutaneous reactivity
- Systemic toxicity (acute)
- Hemolysis Study, Direct Contact
- Complement Activation Assay
- Thromboresistance Study

The test results demonstrate that the Creganna-Tactx Lotus™ Introducer Set meets the requirements in the applicable standards and specifications, and is substantially equivalent to legally marketed predicate device.

Clinical studies were not deemed necessary since *in vitro* and *in vivo* testing and a literature review were sufficient to demonstrate safety and effectiveness by way of comparison to a legally marketed predicate device.

Summary of Substantial Equivalence

Creganna-Tactx Medical believes the Creganna-Tactx Lotus™ Introducer Set is substantially equivalent to the predicate product. The intended use, method of operation, methods of construction and materials used, are either identical or substantially equivalent to existing legally marketed predicate products.